



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 24, 2014

Integra LifeSciences Corporation
Mr. Brian Hoy
Project Manager, Regulatory Affairs
4900 Charlemar Drive, Building A
Cincinnati, OH 45227

Re: K142238

Trade/Device Name: MAYFIELD Skull Clamp

Regulation Number: 21 CFR 882.4460

Regulation Name: Neurosurgical Head Holder (Skull Clamp)

Regulatory Class: Class II

Product Code: HBL

Dated: August 25, 2014

Received: August 26, 2014

Dear Mr. Brian Hoy,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Peña-S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K142238

Device Name

MAYFIELD Skull Clamp

Indications for Use (*Describe*)

The MAYFIELD Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Integra LifeSciences Corporation
Premarket Notification Traditional 510(k)
MAYFIELD Skull Clamp

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 is provided below.

807.92(a)(1) - Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone number	513-533-7544
Fax number	513-271-0957
Establishment Registration Number	3003418325
Name of contact person	Brian Hoy
Date prepared	August 8, 2014
Manufacturing Site Information	
Name	Integra LifeSciences Corporation
Address	4900 Charlemar Drive, Bldg. A Cincinnati, OH 45227
Establishment Registration Number	3004608878
807.92(a)(2) - Name of device	
Trade or proprietary name	MAYFIELD® Skull Clamp
Classification name	Holder, Head, Neurosurgical (Skull Clamp)
Common or usual name	Neurosurgical head holder (skull clamp)
Classification panel	Neurology
Product Code(s)	HBL
Regulation Number	882.4460
Device Class	Class II
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	MAYFIELD Skull Clamp (K120633)
807.92(a)(4) - Device description	
	<p>The MAYFIELD Skull Clamp is a cranial stabilization device, designed to provide rigid skeletal fixation.</p> <p>The MAYFIELD Skull Clamp supports a 2-pin rocker arm, which allows for 360° rotation under full impingement force. The device has the means for skull pin force</p>

	<p>determination via an integral force gauge in the torque screw opposite the rocker arm. The device is equipped with an adjustable ratchet arm to allow the surgeon to adjust the clamp for various head sizes. The ratchet arm is released by side-acting pawls, which facilitate the removal of the clamp from the patient.</p> <p>The MAYFIELD Skull Clamp does not directly contact the patient. The MAYFIELD Skull Pins used with the skull clamp are the components which contact the patient. The skull pins are supplied separately and are not the subject of this 510(k).</p> <p>The MAYFIELD Skull Clamp is intended to be used non-sterile. It can be autoclaved and cleaned using detergents ranging from a pH of 3 to a pH of 11 as part of the cleaning and decontamination process.</p>
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807.92(a)(5) Intended use of the device

Indications for use	The MAYFIELD Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.
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807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Design	MAYFIELD Skull Clamp	Predicate MAYFIELD Skull Clamp (K120633)
Shape	Parallelogram	Same
Adjustment for various head sizes	Ratchet arm is adjustable	Same
Load Range	0-80 lbs	Same
80 lb force applicator	Yes	Same
Three point fixation	Yes	Same
	MAYFIELD Skull Clamp	Predicate MAYFIELD Skull Clamp (K120633)
Rocker Arm		
2 pin	Yes	Same
360° rotation under full impingement force	Yes	Same
Removable	No	Same
Secured using the swivel locking knob	Yes	Same
Child Rocker Arm	No	Yes (Catalog No. A-3059 C only)

Integra LifeSciences Corporation
 Premarket Notification Traditional 510(k)
MAYFIELD Skull Clamp

Hinged base plate	No	Same
Clamp Release	Side acting pawls	Same
Adjustment knob	No	Same
Multiple pawls	Yes	Same
Target Patient Population	Not recommended for children under 5 years of age	Same
Materials	PEEK / Glass fiber composite Radel R (Polyphenylsulphone) Teflon Hastelloy Stainless Steel Silicone	Same
Cleaning/ Decontamination	Intended to be used non-sterile. Intended to be cleaned by user between uses.	Same
	pH range 3-11 and high temps	Same
	Can be autoclaved	Same
	Disinfection: Pre cycle vacuum at 2psia then steam disinfect at 132°C to 134°C for 4 minutes	Same
	Decontamination: Immersion in bleach solution for 1 hour then autoclave at 134°C for 18 minutes to 1 hour	Same
Imaging Modality	Non-radiolucent	Same
	MAYFIELD Skull Clamp	Predicate MAYFIELD Skull Clamp (K120633)
Where Used	Used in the operating room of the hospital.	Same
	Also used in the diagnostic and or the intra-operative operating suite.	Same
Pins	Uses existing MAYFIELD Skull pins	Same
Accessories	None	Same

807.92(b)(1-2) NONCLINICAL TESTS SUBMITTED	
Test	Result
Skull Clamp Static Load – Verifies the ability of the skull clamp to sustain an 80lb load to a 2x factor of safety	Pass – The clamp supported 160 lb static load for no less than 24 hours without mechanical failure.
Skull Clamp Load Loss – Verifies the ability of the skull clamp to maintain a user defined load in use	Pass – The clamp provided a static clamping force of 80 lbs for 24 hours without a loss of loading greater than 5%.
Skull Clamp Transient Torque – Verifies the ability of the skull clamp to resist transient torque while in use	Pass – The swivel locking mechanism was capable of withstanding a dynamic torque of 20 lb/ft for 30 seconds without mechanical failure.
Skull Clamp Swivel Static Torque – Verifies the ability of the skull clamp to resist applied torque while in use	Pass – The swivel locking mechanism was capable of withstanding a static torque of 10 lb/ft for 24 hours without slippage or mechanical failure.
Skull Clamp Vertical Shear – Verifies the ability of the skull clamp to support an applied vertical load	Pass – The loading mechanism was capable of withstanding a vertical shear loading of at least 100 lbs at 80 lbs pin loading.
WHO Performance Test – Verifies the ability of the skull clamp to withstand repeated cycles of the WHO (World Health Organization) recommended guidelines for decontamination without mechanical failure	Pass – The skull clamp was capable of withstanding 15 autoclave cycles of 134°C for 60 minutes in accordance with the WHO decontamination process without mechanical failure.
Reliability Test – Verification that the locking knob mechanism meets manufacturer's warranty period.	Pass - The Skull Clamp met a minimum MTBF (Mean Time Between Failures) of 1 year, at a 95% confidence level.
Unlock torque Over Time – Verification that the index lock meets internal requirements.	Pass – The product met internal specification for unlocking after prescribed force was applied over time
Biocompatibility	No component contacts the patient; therefore, no biocompatibility studies are required
807.92(b)(3) CONCLUSIONS DRAWN FROM NON-CLINICAL DATA	
Testing confirmed that the performance of the MAYFIELD Skull Clamp meets the product specifications of the device.	